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EXAMINER	
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ART UNIT	PAPER NUMBER
1638	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/064,001	DAN ET AL.	
	Examiner	Art Unit	
	KEITH O. ROBINSON	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of claim 1 and cancellation of claim 8, filed November 3, 2009, have been received and entered in full.

Claims 1-7 and 9-16 are pending.

Applicant's arguments, see page 11 of 'Remarks' filed November 3, 2009, with respect to the 'Obvious type double patenting' rejection of claim 1 on pages 7-8 of the Office Action mailed August 3, 2009 have been fully considered and are persuasive. The rejection has been withdrawn.

It is suggested, for clarity purposes, that the limitation "wherein the explant is a wheat mesocotyl explant" be removed and replaced at the end of the 3rd line after the word "meristems".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 9-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al (Planta 187: 483-489, 1992), in view of Bowen et al (U.S. Patent No. 5,736,369, April 7, 1998), in view of Cheng et al (Plant Physiology 115: 971-

980, 1997), Bartok et al (Plant Cell, Tissue and Organ Culture 22: 37-41, 1990), in view of Weeks et al (Plant Physiol 102: 1077-1084, 1993).

The claims read on a method comprising culturing a wheat mesocotyl explant on bud inducing media, transforming the explant via introducing exogenous DNA, inducing elongation of buds into shoots and roots and regenerating plants (claims 1 and 13).

Limitations include cytokinins and auxins in the multiple bud inducing media (claims 2-6); plurality of meristems containing scutellar node (claim 7); exogenous DNA comprising a nucleic acid encoding a protein capable of conferring resistance to a selection agent and selecting for plants containing the protein conferring resistance to said selection agent (claims 9 and 10); introducing exogenous DNA via biolistic particle bombardment or *Agrobacterium*-mediated transformation (claims 11, 12, 14 and 15) and selecting plants containing the exogenous DNA (claim 16).

Zhong et al teach culturing corn mesocotyl explants on bud inducing media. See, for example, page 484, 2nd column, 1st paragraph of 'Results' of the Zhong et al reference where it teaches a basal medium, MS, containing BA (a cytokinin, as evidenced on page 7, paragraph 0034 of the specification) and 2,4-D (an auxin, as evidenced on page 7, paragraph 0034 of the specification). Also, see, for example, page 484, Figure 1 where it depicts culturing explants in a multiple bud inducing media. Zhong et al also teach "[o]ur work shows that the corn-shoot meristem can be committed to form either clumps of multiple shoots or somatic embryos in vitro by manipulating the concentrations of BA [cytokinin] and 2,4-D [auxin] in the culture medium" (see page 488, 1st column, last paragraph).

Zhong et al teach inducing elongation of buds into shoots and roots and regenerating plants. See, for example, page 484, 1st column, 2nd and 3rd paragraphs where it teaches inducing adventitious shoot formation by transferring shoot-tip explants to MS basal medium. See, for example, page 484, Figure 1 where it teaches rooted corn plants produced after shoot development.

Zhong et al teach plurality of meristems containing the scutellar node. See, for example, page 483, 2nd column, last paragraph where it teaches "[t]he position of the shoot tip of the seedling inside the coleoptile could be determined by the localized enlargement of the seedling at the junction of mesocotyl and coleoptile". The specification teaches, "mesocotyl refers to the internode between and including the scutellar node, and the coleoptile" (see page 5, paragraph 0029). The specification also teaches "[m]eristem tissue is a tissue that produces cells that undergo differentiation to form mature tissues" (page 5, paragraph 0029). As a result, it would have been obvious to one of ordinary skill in the art that meristematic tissue is inherent in the explants taught by Zhong et al.

Zhong et al teach culturing explants in a multiple bud inducing media suitable for inducing a plurality of buds. See, for example, page 483, 'Materials and methods' last sentence to page 484, lines 1-10 where it teaches multiple shoot clumps arising from explants cultured on supplemented MS basal medium.

Zhong et al do not teach wheat mesocotyl explants, introducing exogenous DNA, exogenous DNA comprising a nucleic acid encoding a protein capable of conferring resistance to a selection agent and selecting for plants containing the protein conferring

resistance to said selection agent, introducing exogenous DNA via *Agrobacterium*-mediated transformation.

Bartok et al teach wheat mesocotyl explant. See, for example, page 39, Figure 2 where it teaches mesocotyls of mature wheat embryos. Bartok et al use the wheat mesocotyl explants for wheat calli formation that are used to form plantlets regenerated via organogenesis (see 'Abstract'). One of ordinary skill in the art would have been motivated to combine the teachings of the Bartok et al reference with the teachings of the Zhong et al reference to produce multiple wheat plants from an explant because Zhong et al shows that corn-shoot meristem can be committed to form clumps of multiple shoots and Bartok et al teach wheat mesocotyl explants. Therefore, it would have been obvious to one of ordinary skill in the art to replace the teachings of Zhong et al using corn-shoot meristems with the teachings of Bartok et al using wheat mesocotyl explants because both meristems and explant tissue are used to regenerate plantlets. Thus, it would have been obvious to substitute one method of producing plantlets for another method. Although Zhong et al teaches corn, the method of Zhong et al would be broadly applicable to other plants, particularly wheat because it is a moncot like corn.

Bowen et al teach introducing exogenous DNA into a plurality of meristems. See, for example, column 2, lines 45-46 where it states, "foreign DNA can be introduced into a plurality of meristems, at least some of which differentiate...to form a plurality of plantlets".

Weeks et al teach exogenous DNA comprising a nucleic acid encoding a protein conferring resistance to a selection agent, selecting for plants containing the protein and

introduction of said DNA via biolistic particle bombardment. See, for example, page 1078, 1st column, last paragraph where it teaches exogenous DNA, namely the *bar* gene that encodes the enzyme PAT which inactivates phosphinothricin, the active ingredient of the herbicides bialophos and Basta. See, for example, page 1079, 1st column, 3rd paragraph where it teaches a selection method based on spraying transformed wheat plants with herbicide to determine which wheat plants were resistant. See, for example, page 1078, 2nd column, 2nd paragraph where it teaches introduction of DNA via biolistic particle bombardment.

Cheng et al teach introduction of exogenous DNA into wheat via *Agrobacterium*-mediated transformation. See, for example, page 971, last paragraph to page 972, 2nd column, 2nd paragraph.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teachings of the above cited references to produce a method of producing multiple transgenic wheat plants from a single explant.

One of ordinary skill in the art would have been motivated to combine these teachings because Bowen et al teach "foreign DNA can be introduced into a plurality of meristems...to form a plurality of plantlets" (see column 2, lines 45-47). Thus, one of ordinary skill in the art would have been motivated to produce transgenic plants from an explant.

In addition, one of ordinary skill in the art would have had a reasonable expectation of success based on the success of Zhong et al in producing "[a]bout 20-50 shoots…per shoot-tip explant within four weeks of culture" (see page 486, 1st column,

last line to 2nd column, 1st line). Though Zhong et al teach multiple corn plants produced from a single explant, one of ordinary skill in the art would expect that multiple wheat plants would also be produced from a single explant because Bowen et al teach that maize and wheat are monocotyledonous plants (see, for example, column 1, lines 30-32); thus, one of ordinary skill in the art would appreciate that methods used for maize can be used for wheat.

Response to Arguments

1. The mesocotyl explant of Bartok is not distinct from that of the present invention

Applicant argues that the corn explant used in the Zhong et al reference does not comprise a node, let alone a mesocotyl, which is an internode (stem) structure and is located below the node (see page 5, last paragraph to page 6, line 2 of 'Remarks' filed November 3, 2009).

This is not persuasive. Though the Zhong et al reference teaches corn explant, the Bartok reference does explicitly teach wheat mesocotyl explants. It would have been obvious to one of ordinary skill in the art to replace the teachings of Zhong et al using corn-shoot meristems with the teachings of Bartok et al using wheat mesocotyl explants because both meristems and explant tissue are used to regenerate plantlets. Thus, it would have been obvious to substitute one method of producing plantlets for another

method. The method of Zhong et al would be broadly applicable to other plants, particularly wheat because it is a moncot like corn.

Applicant argues that the mesocotyl explant of the Bartok reference is not equivalent to the mesocotyl of the claimed invention because Bartok apparently contemplates cuts which leave the mesocotyl attached to the scutellum, but removes most of the germ, resulting in removal of the coleoptile, shoot apex, radicle and associated nodes and meristems wherein the claimed invention includes germ tissue (i.e. mature or immature embryonic tissue) and the associated plurality of meristems (see page 6, 1st full paragraph of 'Remarks' filed November 3, 2009).

This is not persuasive. The specification teaches "mesocotyl sections are obtained by removing the upper portion of the coleoptile and roots around the crown region from the germinating seedling...[and [i]t is important when excising the mesocotyl explant to leave a whole piece of the scutellum attached to the explant (see page 5, paragraph 0030). The mesocotyl explant of Bartok was obtained by removal of most of the germ tissue so that only mesocotyl remained on the scutellum. The term "most of the germ" is not defined in the Bartok reference, so it is unclear how Applicant can assert that the coleoptile, shoot apex, radicle and associated nodes and meristems have been removed from the Bartok wheat mesocotyl. The mesocotyl taught in the Bartok reference appears to be essentially the same as that of the instant invention.

2. Combining Bartok with Zhong does not change the principle of operation of Zhong

Applicant argues that combining Bartok with Zhong would change the principle of operation of Zhong if the explants of Bartok were utilized with the tissue culture conditions of Zhong let alone if other aspects of Bartok's teachings were utilized with Zhong (see page 7, 1st paragraph of 'Remarks' filed November 3, 2009).

This is not persuasive. Both references teach plantlet regeneration via organogenisis and both references teach plant growth media comprising cytokinins and auxins. One of ordinary skill in the art would have had the ability to modify the tissue culture conditions of Zhong to utilize the wheat mesocotyl explants of Bartok because Zhong teaches "[g]entotypic differences in plant regeneration in corn cultures can be circumvented by altering the concentration of growth regulators in the culture medium (see page 488, 2nd column, last paragraph). In addition, Zhong et al teach various concentrations of an auxin and a cytokinin in a growth regulator concentration and that different corn genotypes produce different results. One of ordinary skill in the art would have had the ability to produce plant growth media for wheat plants based on the method of Zhong by comparing different auxin and cytokinin concentrations. Therefore, by modifying the teachings of Zhong et al, one of ordinary skill in the art would have been able to combine the teachings of Zhong et al with those of Bartok et al to produce the claimed invention.

See MPEP 2141(II) (C) where it states, "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton."KSR, 550 U.S. at ___, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."Id. Office personnel may

also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ."Id. at ___, 82 USPQ2d at 1396".

In the instant case, one of ordinary skill in the art would have had the ability to modify the tissue culture conditions of Zhong to utilize the wheat mesocotyl explants of Bartok because Zhong teaches "[g]entotypic differences in plant regeneration in corn cultures can be circumvented by altering the concentration of growth regulators in the culture medium (see page 488, 2nd column, last paragraph) and one of ordinary skill in the art would have had the ability to modify the tissue culture conditions of Zhong to use the wheat mesocotyl explant of Bartok.

3. A skilled worker would have had an expectation of success in combining Zhong and Bartok

Applicant argues that it is unclear how the teachings of the cited references might be combined since the growth conditions of the Zhong reference are designed to effect direct organogenesis by growth in the presence of benzyladenine (a cytokinin), while on the other hand the Bartok reference describes conditions for callus induction of wheat explants and subsequent shoot formation, initially utilizing only an auxin without cytokinin and then transferring developing calli to hormone-free medium (see page 8, 1st paragraph to page 9, lines 1-14 of 'Remarks' filed November 3, 2009).

This is not persuasive. The claims do not prohibit callus induction, so one of ordinary skill in the art would have had a reasonable expectation of success in combining the Bartok reference with that of the Zhong reference because both corn and

wheat are monocotyledons and one of ordinary skill in the art would have had the understanding that both can be utilized in tissue culture techniques to produce plants. Though the two references use different tissue culture parameters, both references teach the use of media containing cytokinins and/or auxins used to produce plantlets. As stated above, one of ordinary skill in the art would have had the ability to modify the tissue culture conditions of Zhong to utilize the wheat mesocotyl explants of Bartok because Zhong teaches "[g]entotypic differences in plant regeneration in corn cultures can be circumvented by altering the concentration of growth regulators in the culture medium (see page 488, 2nd column, last paragraph) and one of ordinary skill in the art would have had the ability to modify the tissue culture conditions of Zhong to use the wheat mesocotyl explant of Bartok. One of ordinary skill in the art would have been able to use Figure 1 on page 484 of the Zhong reference to replace the seedling shoot tip explants taught by Zhong with the mesocoytl explants taught by Bartok because both references teach monocotyledon explant material.

In addition, one of ordinary skill in the art would have had a reasonable expectation of success based on the teachings of various concentrations of growth regulators in growth media in maize as taught on page 484, Figure 1 of Zhong and one of ordinary skill in the art would have been able to modify the teachings of Zhong to accommodate the teachings of Bartok.

4. The method of the present invention does not provide unexpected results

Applicant argues the claimed invention allows a skilled worker to rapidly and efficiently multiply the amount of tissues useful for transforming cells and regenerating plants and thus by 3-5 weeks multiple bud clumps arising from pre-existing meristem could be transferred to a shoot elongation medium for rooting without a need for *de novo* meristem formation or callus formation (see page 9, 1st paragraph to page 10, line 9 of 'Remarks' filed November 3, 2009).

This is not persuasive. Applicant's arguments regarding unexpected results are drawn to the formation of multiple bud clumps from pre-existing meristem by 3-5 weeks. In contrast, the claims are broadly drawn to a method comprising culturing a wheat mesocotyl explant on bud inducing media, transforming the explant, inducing elongation of buds into shoots and roots and regenerating plants. The claims are not drawn to rapidly and efficiently multiplying the amount of tissues useful for transforming cells and regenerating plants wherein by 3-5 weeks multiple bud clumps arise from pre-existing meristem that can be transferred to a shoot elongation medium for rooting without a need for *de novo* meristem formation or callus formation.

The claims are drawn to a method of producing multiple transgenic wheat plants from a single explant comprising culturing a wheat mesocotyl explant in a multiple bud inducing media, introducing exogenous DNA into more than one of a plurality of buds, removing buds from the first media and transferring to a second media suitable for the induction of elongation of buds into shoots, harvesting and transferring shoots to a media for root development and culturing transferred shoots to produce multiple transgenic wheat plants. As discussed above, the combined references teach or

suggest each of the claimed steps. Applicant's invention does not provide evidence of unexpected results because Zhong et al teach the formation of multiple shoots in corn in 4 weeks. One of ordinary skill in the art would have had a reasonable expectation that wheat plants would produce multiple shoots as well because it too is a monocotlyledon plant like corn.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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